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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,974	02/13/2002	Sheldon R. Pinnell	SKIC001	6893

7590 07/16/2002

Lynn E. Barber
Post Office Box 16528
Fort Worth, TX 76162

EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/074,974	Pinnell et al.
Examiner	**Art Unit**
Patricia Patten	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 30, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *1-15, 27, and 28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election of Group III, claims 16-26 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-15 and 27-28 have been withdrawn from further consideration on the merits as they are now drawn to a non-elected invention.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 26 states wherein the pH of the composition is about 2.0 to 4.5. There is no teaching in the Specification wherein the pH of the composition is 2.0. Further, pH 2.0 is not in the accepted pH range for topically applied cosmetics. Clarification is necessary.

Claim Rejections - 35 USC § 112

Claims 16-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 20 - 22 state 'vitamin E component.' Does this mean any part of the vitamin E? Or does it mean derivatives of vitamin E? Although claims 21 and 22 limit the 'vitamin E component' to species such as tocopherols, the term 'component' remains indefinite. For example, hydrogen is a 'component' of vitamin E. Clarification is needed in order to avoid confusion.

Claims 18 and 20 are indefinite in that they depend upon a non-elected claim. Applicant is asked to re-write the claims in order to recite the missing extraction steps set forth in claim 1.

Claims 16-17, 19 and 21-26 all recite the term 'extract' without clearly indicating which extract is intended. There are numerous extraction protocols known in the art, and each respective extraction protocol will necessarily produce distinct products which may have different effects when administered to an individual. Thus, the meets and bounds of the term 'extract' is not clearly delineated and one of ordinary skill in the art may have trouble

ascertaining exactly what other extracts, besides the ones taught in the Instant Specification as filed. Limitation to the type of extract; i.e., alcoholic is necessary.

Claim 18 recites 'the olive-leaf extract..'. This phrase lacks antecedent basis in claim 16 in that claim 16 recites 'olive extract.'

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17, 19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (US 5,378,461) in view of Bates (US 4,704,280) in light of Ganguli et al. (US 5,998,641)*. Claims 16-17, 19 and 21-26 are drawn to a composition comprising an olive extract, L-ascorbic acid, vitamin E and vitamin C in specific proportions. Claims are further drawn to wherein the extract is an olive leaf extract, wherein the vitamin E component comprises α-tocopherols or tocotrienols, wherein the olive extract comprises an antioxidant phenolic compound, wherein the antioxidant is oleuropein or hydroxytyrosol, wherein the product

contains a carrier such as water or alcohol, wherein the composition further comprises zinc sulfate, and wherein the pH of the product is about 2.0 to 4.5.

Neigut (US 5,378,461) disclosed a topical composition which included olive oil (an 'olive extract' found in the fruit and leaves of the olive plant) along with vitamins A, D, and E (α-tocopherol). Olive oil intrinsically contained oleuropein as disclosed by Ganguli et al.* (col.1, lines 24-48) Neigut did not specifically disclose wherein the pH of the product was about 2.0 to 4.5, wherein the product contained vitamin C, nor did Neigut disclose the particular amounts of each respective ingredient in the composition.

Addition of vitamins such as vitamins A, E and C was common in the art of cosmetology. Bates (US 4,704,280) for example disclosed a cosmetic lotion containing aloe vera and zinc (Bates taught that zinc salts and oxides were suitable - col.3, lines 16-19) along with vitamins C, E and A (col's 1 and 2). It is well known that zinc is an acceptable astringent and is used in many topical cosmetic formulations as evidenced by Bates.

One of ordinary skill in the art would have been motivated to have added zinc and vitamin C into the topical formulation proposed by Neigut in order to have formulated a product with additional beneficially active ingredients. The inclusion of vitamin C and zinc would have offered further antioxidant properties, as well as astringent properties to the cosmetic formulation, thereby making the product more efficacious, as well as more marketable to the consumer.

Although neither reference taught wherein the zinc was specifically supplied from zinc sulfate, Bates did teach that any zinc salts would have been suitable in the formulation. Because zinc sulfate is a basic zinc salt, one of ordinary skill in the art would have had a reasonable expectation that zinc sulfate would have proven a suitable candidate for the composition.

Although Neigut was silent as to wherein the pH of the product was about 2.0 to 4.5, it is known that a pH of about 4.5 is within the acceptable pH range for topical application. A pH of about 4.5 would be mildly acid, however, would not readily damage skin cells. Because this pH is in the pharmaceutically acceptable range, it would have been a matter of judicious selection on the part of the ordinary artisan to formulate the product at a pH of about 4.5 in order to provide a topically administered composition which was suitable for application to the skin.

Neigut did not specifically teach wherein the formulation was prepared with a carrier such as water or alcohol or a surfactant for example. However, it was well known to emulsify products which contained oils via use of water or alcohol to form emulsions. The emulsion form would have created a more creamy version of the composition; i.e, lotions and creams. One of ordinary skill in the art would have been motivated to have created emulsions and creams with the composition of the Instant claims in order to vary the form of the product, thereby making it more appealing to the consumer.

Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the

composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment.

Claims 16, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisner (AU 200159311 A - English Abstract) in view Neigut (US 5,378,461), Bates (US 4,704,280), Shasha et al. (1960), Fleming et al. (1969) and Fleming et al. (1973). Claims 18 and 20 are drawn to wherein the olive-leaf extract is prepared by the method of claim 1 (please see rejection under 35 U.S.C. 112 Second paragraph *supra*). Claims 18 and 20 describe wherein the olive-leaf extract is obtained by a method comprising inactivation of the enzymes in the leaves, extraction with a non-aqueous solvent and concentrating, and performing an additional extraction to create a final product.

Meisner (AU 200159311 A) disclosed a topical composition for treating psoriasis including oleuropein (English Abstract). Thus, oleuropein, which is deemed by the Examiner to be an 'extract' of olive leaves, (i.e.; obtained via chemical separation methods) was a common ingredient in topical cosmetic/pharmaceutical formulations. Meisner did not teach wherein the olive leaf extract (in this case, oleuropein) was produced by the method according to claim 1 or wherein the composition contained L-ascorbic acid, vitamin E and vitamin C in specific proportions.

The teachings of Neigut and Bates were discussed *supra*.

Olive extracts and purification of the bitter principal contained in said extracts, known as oleuropein, were known at the time the instant invention was made. Shasha et al. proposed the extraction of oleuropein via extraction with boiling acetone, precipitation with basic lead acetate, adsorption on charcoal, performing paper chromatography and crystallization from ethyl acetate (p.1948). Thus, Shasha et al. inactivated the enzymes in the olives via a non-aqueous solvent, concentrated via adsorption onto charcoal, and performed another extraction with a non-aqueous solvent (ethyl acetate) (thereby obviating the limitations of the method for extraction).

Fleming et al. (1973) taught that olives intrinsically contained 'debittering enzymes' which degraded bitter compounds such as oleuropein (p.777). Flemming et al. (1963) taught that heating the olives inactivated these 'enzymes' (or 'naturally occurring inhibitory substance') (p.856).

It was well known in the art that olives, as well as olive leaves contained a bitter principal known as oleuropein. It was also known that olive leaves intrinsically possessed oleuropein and methods for extracting oleuropein while deactivating 'debittering' enzymes were known in the art.

One of ordinary skill in the art would have been motivated to have created a topical formulation for the skin comprising an olive extract containing oleuropein which was devoid of oleuropein degrading enzymes because one of ordinary skill in the art would have been reasonably appraised that the inactivation of these enzymes would provide a product which contained oleuropein at a higher activity level than that of an extract which contained the enzymes, thus, making the product more efficacious for the consumer/patient. The ordinary artisan would have recognized that inactivation of the enzymes via heat, or boiling or alcohol treatment would have ceased the enzymes from degrading the product during extraction, and further eliminated any subsequent enzyme degradation after extraction due to these enzymes.

As stated *supra*, all of the ingredients were well known to be formulated into topical/cosmetic preparations to treat dry skin and/or psoriasis. One of ordinary skill in the art, with the references before him would reasonably conclude that the instant ingredients would have beneficially treated psoriasis and/or dry skin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

* USED TO RELAY AN INTRINSIC PROPERTY

7/10/02

CHRISTOPHER R. TATE
PRIMARY EXAMINER